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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 30-32 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed August 21, 2008 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Claims 1-11 and 30-32 remain pending and under examination. Claims 1 and 7 are amended.

Applicant's arguments, filed August 21, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 30-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.2-5 of the previous Office Action dated May 23, 2008, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that support for this step of the method can be found at p.1, l.3-6 and p.2, l.17-21, wherein the specification discloses that the instant methods are directed to the treatment of obesity and conditions of overweight in mammals, especially the pediatric population. Applicant relies upon Merriam-Webster to define the term "treat" as "caring for or dealing with medically or surgically, such as to treat a disease" to show that, in order to care for or deal with a condition such as obesity and conditions of overweight, the obesity and the conditions of overweight must be identified. Still further, Applicant submits that the specification describes suitable means for identifying an obese or overweight mammal and references the disclosure of body mass index (BMI) in the specification as overweight if between 25 and 29.9 or obese if greater than 30.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's position appears to be grounded in the belief that the very disclosure of the term "treating" implies an inherent identification step and, thus, provides support for this newly added limitation. However, as previously stated in the body of the rejection, the administration of the instantly claimed polyunsaturated fatty acid composition to an overweight or obese mammal does not necessarily imply that such an overweight or obese mammal was, in fact, particularly identified as such prior to administration. In other words, it is understood that the "identification" step as claimed would include, for lack of a specific definition by Applicant, physiologic tests and/or measurements of height and weight to determine, e.g., body mass index, percentage body fat, etc. However, such a step of identifying a patient of this type is not necessarily implied since it would be possible to administer the claimed composition to a previously identified or overtly obvious overweight or obese patient without performing the step as instantly claimed. For these reasons, and in view of the lack of a specific teaching, suggestion or disclosure as to the identification of an overweight or obese mammal prior to administration of the instantly claimed polyunsaturated fatty acid composition, Applicant's newly added limitation directed to

the identification of an overweight or obese mammal is not adequately supported, either explicitly or implicitly, by the specification and claims as originally filed.

Secondly, it is also noted that the instant specification discloses a body mass index (BMI) parameter used to define the degree of overweight or obesity. However, even if, *arguendo*, such disclosure was sufficient to provide disclosure of a patient identification step (which the Examiner does not concede), the specific disclosure of a single parameter determination in order to identify an overweight or obese patient fails to be supportive of the broader concept of identifying an overweight or obese patient via *any* identification means. In other words, the disclosure of a specific manner of identifying a patient (which, again, the Examiner does not concede that the reference to BMI constitutes an implicit disclosure of a step of patient identification) fails to provide adequate written support for the generic concept of "identifying" an obese or overweight mammal using any possible identification means. This is, therefore, a clear broadening of the subject matter disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure.

For these reasons *supra*, and those previously set forth at p.2-5 of the Office Action dated May 23, 2008, rejection of claims 1-11 and 30-32 remains proper.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claims 1 and 7 (and the claims dependent therefrom) read upon a "method for decreasing the appetite of an overweight or obese mammal", but Applicant has failed

to connect the preamble objective of decreasing the appetite of an overweight or obese mammal to the mammal actually being treated by the method. For example, it is not clear whether the overweight or obese subject is actually in need of appetite reduction or whether the method is intended for practice in any overweight or obese patient who may or may not be in need of appetite reduction. In other words, Applicant has not made clear on the record whether the overweight or obese mammal in one in need of appetite reduction. As a result, the metes and bounds of the presently claimed subject matter cannot be identified and one of ordinary skill in the art would not have necessarily been reasonably apprised of the scope of the claims.

For these reasons, claims 1-11 and 30-32 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 7 is directed to a method for decreasing the appetite of an overweight or obese mammal comprising identifying said overweight or obese mammal and enterally administering at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid and an amount of long-chain n-6 polyunsaturated fatty acid in relative amounts effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acids independent have 20 or more carbon atoms, and wherein the polyunsaturated fatty acids are administered in the form of a triacylglycerol to treat obesity or overweight in mammals that are obese or overweight.

In particular, it is unclear what is meant by the phrase "in relative amounts effective to decrease the appetite of said mammal". The claims fail to describe to what the amounts are, in fact, relative. For example, are the amounts relative to one another (i.e., the amount of the long-chain n-3 polyunsaturated fatty acid is relative to the amount of the long-chain n-6 polyunsaturated fatty acid)? Or are they relative

to the amount that would be required if it were the only agent to be administered? As a result, the metes and bounds of the presently claimed subject matter cannot be identified and one of ordinary skill in the art would not have necessarily been reasonably apprised of the scope of subject matter for which Applicant is presently seeking protection.

For these reasons, claims 7-9 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135), each already of record, for the reasons of record set forth at

p. 5-12 of the previous Office Action dated May 23, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 1 remains properly included in the present rejection because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood. Accordingly, the teachings of Phinney et al. in view of Visser et al. properly meet Applicant's newly added limitation directed to enteral administration of the claim long-chain polyunsaturated fatty acid with 20 or more carbon atoms in the form of a triacylglycerol "at a time prior to or in conjunction with an appetite-impacting stimulus", because growth of the human body in any of these three stages (i.e., infancy, adolescence, or adulthood) would necessarily be present at *any* time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth. Although Applicant has remarked that an "appetite-impacting stimulus" has been defined as a stressor or stimuli that may increase food intake, such as irregular meal times, sleep deprivation and parental expectations to excel in school and/or sports, it is noted that Applicant has provided only an exemplary list of such stressors in the instant specification and, therefore, given the non-limiting definition that has been provided in the instant specification at p.18, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Phinney et al. fails to disclose a method of enterally administering at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal. Applicant urges that Phinney et al. lacks any disclosure of administering the claimed active agent relative to an "appetite-impacting stimulus" as now required in instant claim 1. Still further,

Applicant again submits that the cited references and the knowledge available to one skilled in the art lacks any apparent reason to combine or modify the references to arrive at the instantly claimed invention (i.e., specifically, enterally administering at the time prior to or in conjunction with an appetite-impacting stimulus to an obese or overweight mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal and treat the obesity or conditions of overweight) and asserts that, although there is potential overlap between the specific diseases, there is nothing in the references to teach or suggest that administering the composition of Phinney et al. will effect the treatment of obesity or overweight.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's argument that Phinney et al. fails to disclose a method of enterally administering at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal is unpersuasive for the following reasons: (1) Phinney et al. explicitly teaches the administration of DHA-containing formulation orally (i.e., "enterally" as in instant claims 1 and 7), such as via capsules, tablets, pills, soft gel-caps, powders, solutions, dispersions or liquids (p.23, l.34-36), (2) Phinney et al. also explicitly teaches the administration of DHA in an exemplary amount of 10-10,000 mg (p.27, l.23-31), which meets Applicant's defined amount of instant claims 5-6 and 10-11 as an amount of the active long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal and (3) Phinney et al. meets the newly added limitation directed to administration "at a time prior to or in conjunction with an appetite-impacting stimulus" because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood such that growth of the human body in any of these three stages (i.e., infancy, adolescence or adulthood) would necessarily be present at *any* time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth and,

therefore, in view of the fact that Applicant has only provided an exemplary list of stimuli that constitute the "appetite-impacting stimulus" as instantly claimed, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary. Accordingly, Applicant's allegation that the reference to Phinney et al. fails to meet these limitations (particularly the newly added limitation of administering the active agent relative to an "appetite-impacting stimulus") of the instant claims is clearly without merit for the reasons enumerated *supra*.

Secondly, Applicant once again urges that there is no apparent reason to combine or modify the cited references to arrive at the instantly claimed invention. This is again unpersuasive. Though it is acknowledged that Phinney et al. does not explicitly teach the reduction in appetite in an obese or overweight mammal or the identification of an overweight or obese mammal, Phinney et al. provides a clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, e.g., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual evidence demonstrating that a subpopulation of such patients suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the intent to reduce C-reactive protein and with the reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Moreover, as stated *supra*, since

products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

Moreover, Applicant clearly admits on the record (see, e.g., p.11 of the Remarks) that the two patient populations of patients with elevated C-reactive protein (i.e., the patient population of Phinney et al.) and patients suffering from obesity and C-reactive protein (i.e., the patient population of Visser et al.) overlap. Though Applicant urges that the two populations may not be strictly identical in that overweight individuals may be otherwise healthy and not suffering from elevated C-reactive protein, there are clearly patients within this population that (1) are obese and (2) have elevated C-reactive protein. In other words, the cited prior art clearly establishes that, of the larger generic population of patients with elevated C-reactive protein (i.e., as in Phinney et al.), a portion of these patients with elevated C-reactive protein are also obese. Accordingly, Applicant's statement that the two patient populations overlap indicates that Applicant is in agreement that, of the patients with elevated C-reactive protein treatable via the method of Phinney et al., there are also patients within this population that are also obese and, thus, the practice of administering the tocopherol-DHA therapy of Phinney et al. for the general purpose of reducing C-reactive protein to treat conditions characterized by elevation of C-reactive protein would also circumscribe its practice in an obese patient population that also exhibits elevated C-reactive protein, which meets the instantly claimed method steps.

Thirdly, note also that the instant claims, in fact, do not require (1) the practice of the method in a patient that is actually in need of appetite reduction or (2) the realization of a reduction in appetite in the mammal to be treated. The claims fail to recite any limitations directed to the therapeutic need of the mammal treated by the method (i.e., that it is actually a mammal in need of appetite reduction; the claims

simply require that the mammal is obese or overweight) and also fail to recite any requirement that the practice of the method steps instantly claimed results in the attainment of appetite reduction. Accordingly, Applicant again is attempting to impute limitations into the claims that are not actually recited. As previously stated, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please see *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Fourthly, and lastly, for the record, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, *as combined*, clearly dictate to the contrary.

For these reasons set forth *supra*, and those previously made of record at p.5-12 of the Office Action dated May 23, 2008, rejection of claims 1-4, 6 and 30-32 is proper.

Claims 7-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135) and Bogentoft (WO 87/03198; 1987), in further view of The Merck Index

(Monograph 792, p.121), each already of record, for the reasons of record set forth at p.12-17 of the previous Office Action dated May 23, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 7 remains properly included in the present rejection because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood. Accordingly, the teachings of Phinney et al. in view of Visser et al. properly meet Applicant's newly added limitation directed to enteral administration of the claim long-chain polyunsaturated fatty acid with 20 or more carbon atoms in the form of a triacylglycerol "at a time prior to or in conjunction with an appetite-impacting stimulus", because growth of the human body in any of these three stages (i.e., infancy, adolescence, or adulthood) would necessarily be present at *any* time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth. Although Applicant has remarked that an "appetite-impacting stimulus" has been defined as a stressor or stimuli that may increase food intake, such as irregular meal times, sleep deprivation and parental expectations to excel in school and/or sports, it is noted that Applicant has provided only an exemplary list of such stressors in the instant specification and, therefore, given the non-limiting definition that has been provided in the instant specification at p.18, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary.

Response to Applicant's Arguments

Applicant traverses the instant rejection, reiterating that neither Phinney et al. nor Visser et al., alone or in combination, teach or suggest each and every limitation of the claimed invention and lack any apparent reason to combine their teachings. Applicant further asserts that Bogentoft and Merck fail to overcome these shortcomings because each reference fails to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty

acid prior to or in conjunction with an appetite-impacting stimulus. Still further, Applicant argues that, since only a portion of the patients treated in Phinney et al. are obese or overweight, there is no reason to select the composition of Bogentoft (which is solely disclosed for treating obesity and overweight) for combination with the composition of Phinney et al. that is directed for use in patients that are not obese or overweight. Applicant urges that Bogentoft only discloses and enables fatty acids having up to 18 carbon atoms and, thus, fails to disclose administering an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms and alleges the Examiner has relied upon hindsight to combine the cited references.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, with regard to Applicant's continued assertions that neither Phinney et al. nor Visser et al., alone or in combination, teach or suggest each and every limitation of the claimed invention and that the rejection lacks any apparent reason to combine their teachings, Applicant is directed *supra* to the response provided in the prior rejection as to why there is an apparent reason to combine the disclosures of Phinney et al. and Visser et al. and further why such a combination of references teaches and suggest each and every limitation of the claimed invention but for the concomitant use of a long-chain n-6 polyunsaturated fatty acid (which is remedied by the citations to Bogentoft and Merck). In the interest of brevity in the record, Applicant is referred *supra* to such an explanation, which will not be repeated herein so as no to burden the record.

Secondly, Applicant's assertion that the cited references to Bogentoft and Merck fail to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them

inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, *as combined*, clearly dictate to the contrary.

Thirdly, Applicant's allegation that there is no reason to employ the composition of Bogentoft for use with the composition of Phinney et al., which is directed for use in patients that are not obese or overweight, is unpersuasive. As previously explained *supra*, the use of the tocopherol-DHA composition of Phinney et al. for the purpose of reducing C-reactive protein in conditions characterized by elevated C-reactive protein in a obese patient population that is known in the art (as evidenced by Visser et al.) to exhibit elevated C-reactive protein is clearly taught and suggested by the cited references to Phinney et al. in view of Visser et al. The concomitant use of the composition of Bogentoft would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention because the composition of Bogentoft is effective for treating obesity and, therefore, such a person would have been motivated to combine the two therapies to (1) reduce levels of C-reactive protein that are known to be elevated in patients with obesity and (2) treat the condition of obesity (i.e., with the composition of Bogentoft) to thereby reduce the precipitating cause of elevated C-reactive protein in such obese patients. Accordingly, in view of such reasons, Applicant's allegation that there is no reason to combine the composition of Bogentoft with that of Phinney et al. is clearly without merit.

Fourthly, Applicant's assertion that Bogentoft is not properly cited prior art because the reference only discloses and enables fatty acids having up to 18 carbon atoms and, therefore, fails to disclose the administration of an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms is unpersuasive because Bogentoft was not cited for a teaching of long-chain n-3 polyunsaturated fatty

acids. This element of the claimed invention is very clearly addressed by the cited reference to Phinney et al. Rather, Bogentoft was cited for its teaching of a composition that comprises fatty acids and animal fats in the form of a triglyceride, of which arachidonic acid (i.e., the long-chain n-6 polyunsaturated fatty acid instantly claimed; see, e.g., instant claim 8) is the major constituent of animal fats. Therefore, the length of the long-chain n-3 polyunsaturated fatty acids in Bogentoft is irrelevant to the fact that the reference clearly teaches a fatty acid composition, of which it is shown that arachidonic acid is a major component (as evidenced by Merck), and, thus, clearly would have been *prima facie* obvious to one of ordinary skill in the art to combine with the composition of Phinney et al. for the reasons described *supra*.

Fifthly, and lastly, Applicant's argument that the Examiner's rationale is grounded in hindsight analysis is clearly unpersuasive. Applicant is reminded that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. However, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Considering the fact that the present rejection under 35 U.S.C. 103(a) relies solely on the knowledge and motivation that was generally available to one of ordinary skill in the art at the time of the invention (as clearly elucidated *supra*, as well as in each of the previous Office Actions) and does not improperly rely upon Applicant's disclosure, the assertion that the present rejection is made with impermissible hindsight reconstruction is unpersuasive.

For these reasons set forth *supra*, and those previously made of record at p.12-17 of the Office Action dated May 23, 2008, rejection of claims 7-9 and 11 is proper.

Conclusion

Rejection of claims 1-11 and 30-32 remains proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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